IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA Alexandria Division

UNITED STATES OF AMERICA)
v.)) CRIMINAL NO.
LUKE J. COUKOS,)
Defendant.)

STATEMENT OF FACTS

At trial, the United States would introduce competent and relevant testimony and exhibits that would prove the following beyond a reasonable doubt.

1. Defendant LUKE J. COUKOS was a pharmacist licensed and residing in the State of Virginia. From October 1999 through August 2000, COUKOS participated in a conspiracy to sell via the Internet, controlled substance and other prescription drugs to consumers in the United States and throughout the world. Through these methods, the defendant and his co-conspirators massmarketed their drugs and services. In furtherance of this conspiracy, COUKOS distributed and dispensed controlled substances and other prescription drugs to customers, along with other individuals and entities with whom he conspired. COUKOS, as pharmacist-in-charge of 2UNet-Mail, doing business as ChoiceRx, a pharmacy in Midlothian, Virginia, personally distributed and dispensed at least 43,066 controlled substance prescriptions, which resulted in the distribution and dispensing at least 146,212 pills of Schedule III drugs and at least 2.5 million pills of Schedule IV drugs, all in violation of federal law. COUKOS also personally distributed and dispensed in interstate commerce at least 9,055 prescriptions of non-controlled prescription drugs. Such drugs were distributed and dispensed to customers in, among other places, Fairfax County, Arlington

County, and Fauquier County in the Eastern District of Virginia. During this time period, Coukos was aware that other pharmacist co-conspirators were also distributing and dispensing controlled substances and other prescription drugs to customers of websites controlled by his co-conspirators.

- 2. Co-conspirator SUNIL K. SETHI hired COUKOS to distribute and dispense the controlled substances and other prescription drugs to customers who ordered drugs over the Internet on the basis of website order forms. VINCENT K. CHHABRA and SABINA K. CHHABRA (also known as SABINA S. FARUQUI), together with other co-conspirators, owned and operated several websites that advertised various controlled substances and other prescription drugs for sale to domestic and international customers.
- 3. The Schedule III substance distributed and dispensed was phendimetrazine, a stimulant for weight loss, sold by its brand name Bontril. The Schedule IV substances distributed and dispensed were phentermine, sold generically and by the brand names Adipex and Ionamin, and sibutramine hydrochloride, sold by the brand name Meridia. These drugs are indicated for weight loss. Other prescription drugs distributed and dispensed included Viagra, Xenical, Propecia, and Celebrex.
- 4. Customers who ordered drugs from the websites were not required to provide a prescription before receiving the controlled substances. Instead, customers filled out an online order form and chose the type, quantity, and dosage of controlled substance the customer wished to purchase. Customers also answered questions about their medical conditions.
- 5. The prescriptions were dispensed under the authorizations of, among others, Dr. William Thompson, Dr. Marvin Brown, Dr. Russell Johnson, Dr. Arturo Portales, and Dr. Laurence Cockerille.

- 6. Under the Controlled Substances Act and its implementing regulations, for a prescription to be valid, a prescription has to be issued for a legitimate medical purpose by an individual acting in the usual course of the professional practice. 21 C.F.R. § 1306.04.
- 7. The prescriptions authorized by the physicians named above were not valid because these physicians had no face-to-face contact with the customer, performed no mental or physical examination, did not take a patient history or perform any diagnostic or laboratory testing, did not check the accuracy of the information customers provided (including their identities, ages, and qualifying medical conditions, such as weight), and did not monitor, or provide any means to monitor, medication response, weight loss, or weight gain. Instead, as COUKOS's co-conspirators well knew and agreed, the controlled substances, as set forth in paragraph 1, were distributed and dispensed for other than legitimate medical purposes and not in the usual course of professional practice. As such, COUKOS's and his co-conspirators' actions violated the Controlled Substances Act.
- 8. Distributing and dispensing controlled substances on the basis of a review of an order form, where there is no previously established doctor-patient relationship, can lead to harm to the person ordering drugs.
- 9. COUKOS and his co-conspirators distributed and dispensed excessive quantities of controlled substances to particular customers on a regular basis. Additionally, COUKOS distributed and dispensed excessive quantities to particular customers that had been authorized by numerous doctors.
- 10. COUKOS knew that because nothing was done to verify a customer's identity before distributing or dispensing drugs, customers were abusing the system and obtaining excessive

amounts of drugs. For instance, COUKOS was aware that customers would change identities to get additional drugs. Despite having this information, COUKOS continued to distribute and dispense drugs sold through the Internet websites.

- 11. At times COUKOS was pressured by his co-coconspirators to dispense and distribute the prescriptions. For instance, sometimes his co-conspirators demanded that he fill prescriptions which he had previously refused to fill because the customer already had an ample supply of drugs. Sometimes his co-conspirators pressured him into shipping drugs to customers living in states for which the pharmacy, 2U-NetMail, did not have a mail order pharmacy license. Additionally, because of the large quantities of prescriptions that came to 2U-NetMail to be filled, and the time pressure to get such prescriptions filled each day, COUKOS was unable to properly review and prepare the prescriptions to be filled on many occasions.
- 12. Under the Federal Food, Drug, and Cosmetic Act, drugs are misbranded if they are shipped in interstate commerce without a valid prescription. 21 U.S.C. §§ 331(a), 333(a)(1), and 353(b)(1).
- 13. During the time COUKOS filled these prescriptions Virginia law required, among other things, that before a prescription could be issued or filled the prescription had to be issued for a medicinal or therapeutic purpose and only to persons with whom the practitioner had a bona fide doctor-patient relationship. Virginia law also required that a prescription could not be filled by a pharmacist unless there was a bona fide doctor-patient-pharmacist relationship. A bona fide doctor-patient-pharmacist relationship was one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to the patient for a medicinal or therapeutic purpose within the course of professional practice. Effective July 1, 2000, a bona fide doctor-patient

relationship was defined to require, among other things, that the physician has performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically. Such physical examination had to be completed by the prescribing physician or by a consulting practitioner prior to issuance of the prescription. From October 1999 through August 2000, COUKOS filled and shipped in interstate commerce at least 52,121 prescriptions, of which at least 16,578 prescriptions were shipped on and after July 1, 2000. Because these prescriptions were authorized and dispensed in the absence of a bona fide doctor-patient-pharmacist relationship, they were not valid prescriptions and therefore were dispensed in violation of the Federal Food, Drug, and Cosmetic Act.

- 14. COUKOS received a total of \$140,318 in wages for distributing and dispensing controlled substances and other prescription drugs ordered by the Internet customers.
- 15. COUKOS used a special skill, his pharmacy license, in order to facilitate the commission of this offense.
- 16. Some customers who received the drugs were harmed from the drugs received through the websites. The customers were misled into believing the Internet consultation process was a legitimate way to prescribe and distribute controlled substances and other prescription drugs. As such, customers were defrauded and were victims of the offense.
- 17. The amount of loss resulting from the fraud from COUKOS's conduct is at least \$5 million.

After consulting with my attorney and pursuant to the plea agreement entered into this day between the defendant, LUKE J. COUKOS, and the United States, I hereby stipulate that the above

Statement of Facts is true and accurate, and that had the matter proceeded to trial, the United State	es
would have proved the same beyond a reasonable doubt.	

Luke J. Coukos Defendant

I am LUKE J. COUKOS's attorney. I have carefully reviewed the above Statement of Facts with him. To my knowledge, his decision to stipulate to these facts is an informed and voluntary one.

William J. Dinkin Counsel for Defendant